NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PHARMACEUTICAL RESOURCES, INC. and PAR PHARMACEUTICALS, INC.	:	Civ. No. 03-3357(DRD)
Plaintiffs,	:	**O P I N I O N**
v.	:	
ROXANE LABORATORIES, INC.	:	
Defendant.	:	

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Debevoise, Senior U.S. District Court Judge

Plaintiffs, Pharmaceutical Resources, Inc., and Par Pharmaceuticals, Inc. ("Par"), brought this suit against Defendant, Roxane Laboratories, Inc., ("Roxane") for infringement of certain claims of U.S. Patent No. 6,593,318 ("the '318 patent") and U.S. Patent No. 6,593,320 ("the '320 patent"). Roxane counterclaimed for declaratory judgment that it did not infringe either patent, that the patents are invalid, and that the patents are unenforceable due to inequitable conduct. On December 19, 2006 the court entered a final judgment granting Roxane's motion for summary judgment of invalidity for lack of enablement and dismissing any remaining counterclaims in the case. The Federal Circuit affirmed the judgment.

Roxane moved to declare this an exceptional case pursuant to 35 U.S.C. § 285 and for an award of attorney fees. The ground for the motion is the claim that Par's attorneys and inventors committed inequitable conduct by intentionally deceiving the United States Patent Office. The Court held a five day hearing. This constitutes the court's findings of fact and conclusions of law.

I. Prosecution History

The ground for Roxane's allegation that this is an exceptional case is that Par engaged in inequitable conduct in the prosecution of the patents in suit. Its inequitable conduct contention can be understood only in the context of the prosecution history.

On April 20, 1998, Par filed patent application No. 09,063,241 ("the '241 Application") in the U.S. Patent and Trademark Office ("PTO"), directed to stable flocculated suspensions of megestrol acetate. The law firm of Ostrolenk, Faber, Gerb & Soffen, LLP ("Ostrolenk") represented Par. Its partner in charge was Edward A. Meilman, Esq. The '241 Application cited as prior art U.S. Pat. No. 5,338,732 issued on August 16, 1994, to Atzinger, et al. ("the '732 Atzinger Patent") and assigned to Bristol-Myers Squibb ("BMS"). The '732 Atzinger Patent describes and claims a flocculated suspension of megestrol acetate that employs a surfactant, polysorbate, and a wetting agent, polyethylene glycol, along with other excipients.

Par included three working examples of flocculated suspensions in the '241 Application. One used the same surfactant that BMS had used, polysorbate, with two different wetting agents, glycerol and sorbitol. The two other examples used another surfactant, docusate sodium, one with the same wetting agent BMS used, polyethylene glycol, and the other having two different wetting agents, glycerol and sorbitol.

Par also listed in the '241 Application many additional compounds that could be used as surfactants to formulate flocculated suspensions of megestrol acetate. The '241 Application stated a stable flocculated suspension of megestrol acetate could be formulated with any surfactant provided one or more wetting agents selected from among polyethylene glycol, propylene glycol, glycerol and sorbitol was also used. Reflecting this breadth, original claim 1 read:

> 1. An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: (a) megestrol acetate, (b) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (c) a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present.

In an Office Action dated March 12, 1999, Examiner Kulkosky rejected all of Par's claims in the '241 Application as obvious (§ 103(a)) and for failing to particularly point out the invention (§ 112).

In response to the obviousness rejection Par wrote:

> In addition, based on the uncertainty of results once any modification in types of ingredients or amounts is made, as discussed in the prior art including Atzinger at al. [sic, et al.] (see also column 4, lines 1-22), a person skilled in the art would not have any reasonable expectation of success in maintaining a stable flocculated suspension of megestrol acetate once a change in the type or amount of surfactant or wetting agent is made.

In response to the § 112 rejection Par wrote:

> all pending claims relate to a composition in the form of a stable flocculated suspension. In addition, applicants did not intend to limit the ingredient concentrations into a specific range since various concentrations of the ingredients disclosed in claim 1 achieved the desired results as discussed herein above.

In a final Office Action dated September 3, 1999, Examiner Kulkosky rejected Par's arguments and continued the rejection of all claims. He pointed out that the claims were not limited to formulations for which Par had demonstrated stability:

> Claims 1-22 are rejected under 35 U.S.C. 112, paragraph 2.
>
> The claims comprise formulas whose stability is not of a definite range. Example 4 at page 13 of the specification indicate [sic, indicates] stability results, whereas the compositions of the claims may not possess the critical property.

On September 29, 1999, Par filed a response to the final Office Action, in which Par amended claim 1 by limiting it to specific ranges of quantities for all claimed ingredients, and by adding a stability limitation. The amended claim read as follows (amendments underlined):

> 1. (Amended) An oral pharmaceutical composition in the form of a stable flocculated suspension in water <u>capable of being redispersed after being allowed to settle at 40° C and 75% relative humidity for a period of three months, said</u>

> composition comprising:
>
> (a) about 10 to 200 mg per ml micronized megestrol acetate;
>
> (b) about 10 to 40% by weight of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and
>
> (c) about 0.0001 to 0.03% by weight of a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present in said composition.

In this manner Par narrowed its claims to both specify ranges of ingredient amounts and defined the stability of the claimed suspensions. On October 1, 1999, in response to Par's September, 1999, Response, Examiner Kulkosky allowed all pending claims. The '241 Application issued on February 22, 2000, as the '065 Patent."

On October 12, 1999, after responding to the final Office Action in the '241 Application, Par filed application Serial No. 09/416,841 ("the '841 Application") as a continuation of the '241 Application.[1] The only claim Par submitted for examination in the '841 Applications was to a method of treating a neoplastic condition by administering the composition of claim 1 as issued in the '065 Patent. The sole claim read:

> A method of treating an anti-neoplastic condition comprising administering to a subject suffering from said condition an oral pharmaceutical composition in the form of a stable flocculated suspension in water capable of being redispersed after being allowed to settle at 40°C and 75% relative humidity for a period of three months, said composition comprising: (a) about 10 to 200 mg per ml micronized megestrol acetate; (b) about 10 to 40% by weight of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) about 0.0001 to 0.03% by weight of a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present in said composition.

On June 21, 2000, Examiner Kulkosky issued an Office Action wherein he rejected the

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[1] All of Par's patent applications at issue are related as continuations or divisions of each other, and all have identical specifications, as do the patents issuing therefrom.

sole pending claim under 35 U.S.C. § 112, first paragraph, stating that the claim was not supported by enabling disclosure since the surfactant would require undue experimentation to choose over all the possible ranges of ingredients and species of same possible for the formula.

In a telephone call with Examiner Kulkosky, Par reminded him that the method claim in the '841 Application relied on the same formulation that he had already allowed in the '065 Patent. Being reminded of that previous conversation, Examiner Kulkosky issued a Notice of Allowance on September 22, 2000. The '841 Application issued as the '356 Patent on July 31, 2001.

On January 9, 2001, Par filed application Serial No. 09/757,261 as a continuation of the '841 Application ("the '261 Application"). In an accompanying preliminary amendment, Par substituted new method claims. Claim 23, the only independent claim, was almost identical to the sole claim allowed in the '841 Application. (*Id.,* pp. 29-30).

The '261 Application was assigned to a different examiner than the '241 and '841 Applications, Examiner Konata George. On December 18, 2001, Examiner George issued an Office Action in the '261 Application rejecting all pending claims for obviousness-type double patenting over Par's '065 and '356 Patents.

On November 15, 2001, prior to receiving Examiner George's December 2001 Office Action, Par submitted a second Preliminary Amendment adding new composition claims. The new claims included new independent claim 41 (which corresponds to claim 19 in the '318 Patent) and new independent claim 63 (which corresponds to claim 41 in the '318 Patent). In Par's remarks, Par told the PTO that:

> A series of new claims covering subject matter disclosed <u>but not previously</u>

> specifically claimed in this application or in the parent applications/patents is being presented for consideration by the Examiner.

(emphasis added).

As part of its inequitable conduct charge, Roxane asserts that the emphasized statement, signed by William Gray of the Ostrolenk firm, is not true. Claims 41 and 63 added to the '261 Application by Par's second Preliminary Amendment stated:

> 41. An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: (a) megestrol acetate; (b) at least two compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) a surfactant.

> 63. An oral pharmaceutical composition in the form of a stable flocculated suspension in water compromising: (a) megestrol acetate; (b) at least one compound selected from the group consisting of propylene glycol, glycerol, and sorbitol; and (c) a surfactant.

Claim 1 from the '241 Application as filed, which Examiner Kulkosky rejected and did not allow stated:

> 1. An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising (a) megestrol acetate, (b) a surfactant, and (c) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, wherein polysorbate and polyethylene glycol are not simultaneously present.

New Claim 41 in the '241 Application is identical to rejected Claim 1 in the '241 Application, except that it requires two compounds from the group of wetting agents consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol rather than "at least one," and drops the proviso that polysorbate and polyethylene glycol are not simultaneously present; and new claim 63 is also identical except that it excludes polyethylene glycol from the group of

wetting agents. When Par submitted these new claims, Par requested their "early consideration and allowance."

Roxane faults Par for not having told Examiner George about Examiner Kulkosky's rejections under 35 U.S.C. §§ 103 and § 112, claiming this was inconsistent with Par's assertion that the new claims were patentable, and also inconsistent with Par's representation that claims of similar scope had never been previously submitted "in the parent applications/patents".

In an Office Action dated February 22, 2002, Examiner George acknowledged that the PTO had received Par's November 2001 second Preliminary Amendment on January 8, 2002, i.e., after the December 2001 Office Action had already issued, and requested a response to that Office Action (the Office Action bearing the signature of Supervisory Examiner Dees and initialed by Examiner George). On March 8, 2002, Par submitted two terminal disclaimers[2] to overcome the double patenting rejection in the December 2001 Office Action. On April 8, 2002, Par submitted a paper that informed Examiner George of a complaint filed against Par in the District of Maryland seeking a declaration that Par's '065 Patent was invalid and not infringed, and Par included a copy of that complaint with its submission.

On April 9, 2002, Examiner George issued a Notice of Allowance of all pending claims in the '261 Application (i.e., claims 23-90) and an Examiner's Statement of Reasons for Allowance stating:

> The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious method [sic] of treating a neoplastic condition comprising administering to a subject suffering from said condition an oral

[2] A terminal disclaimer disclaims any term of a patent that would otherwise extend beyond the term of a specified patent and is sufficient to overcome an obviousness-type double patenting rejection over that specified patent.

> pharmaceutical composition in the form of a stable flocculated suspension in water capable of being redispersed after being allowed to settle at 40°C and 75% relative humidity for a period of three months, said composition comprising: (a) micronized megestrol acetate; (b) about 10 to 40% by weight of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) about 0.0001 to 0.03% by weight of a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present in said composition.

Because this Statement of Reasons for Allowance refers to the claims as specifying ranges of ingredient amounts and defining the stability of the suspensions, it appears that Examiner George was addressing the patentability of only the narrow claims from Par's first Preliminary Amendment, and not the new, broader claims submitted with Par's second Preliminary Amendment.

By Notice dated April 24, 2002, the PTO withdrew the '261 Application from issuance because of an impending interference between the '261 Application and a patent application owned by another party, Alpharma.[3] On April 26, 2002, Par, not yet aware of the April 24, 2002 withdrawal from issuance, filed with the PTO a request for expedited patent issuance based on the April 9, 2002, Notice of Allowance. At the same time Par submitted a document captioned Comments on Statement of Reasons for Allowance in which Par noted that Examiner George had allowed numerous claims, for example, new claim 63 added in the second Preliminary Amendment, which were broader in scope than the claim whose language Examiner George quoted in his Statement of Reasons for Allowance. As part of its inequitable conduct argument, Roxane again notes that Par did not disclose Examiner Kulkosky's prior rejection of claims

[3] An interference is a PTO proceeding to determine priority of inventorship as between a patent application and one or more other applications claiming overlapping subject matter. See U.S.C. § 135.

substantially identical in scope to the broad claims allowed by Examiner George.

On May 15, 2002, the PTO issued a notice of interference for the '261 Application. On October 23, 2002, after the interference was resolved in Par's favor, Examiner George issued a new Notice of Allowance for the '261 Application, but did not address Par's April 26, 2002, Comments on Statement of Reasons for Allowance.

On November 27, 2002, Par filed a document titled Comments on Statement of Reasons for Allowance, in which Par raised the same issue first raised in Par's April, 2002, Comments on Statement of Reasons for Allowance, and in which it confirmed a telephone interview with Examiner George in which he had agreed to issue a Supplemental Notice of Allowance clarifying the reasons for allowance. Without such a restatement of reasons to reflect the language of the new, broader claims, those claims would have been vulnerable to attack.

On March 24, 2003, Examiner George issued a Supplemental Notice of Allowability and a Statement of Reasons for Allowance in which he stated:

> In addition to the reasons given in the previous office action (paper No. 14) the claims are allowable because the prior art does not teach, disclose nor make obvious an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: megestrol acetate, at least one compound selected from the group consisting of polyethylene [sic, polyethylene glycol,] propylene glycol, glycerol, and sorbitol; and a surfactant.

Roxane faults Par for failing to bring to Examiner George's attention the fact that the prior art '732 Atzinger Patent disclosed a megestrol acetate suspension made with polyethylene glycol and the surfactant polysorbate.

On April 30, 2002, Ostrolenk, acting on behalf of Par, filed application Serial No. 10/136,823 ("the '823 Application") as a division of the '261 Application. The '823 Application

was accompanied by a Preliminary Amendment with claims limited to methods of making stable flocculated suspensions of megestrol acetate. The only independent claim in the Preliminary Amendment read as follows:

> A method of preparing an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant, provided that the combination does not consist of polyethylene glycol and polysorbate; and combining the solution with megestrol acetate.

As is evident, except for the characterization of the claim as a method for preparing a pharmaceutical composition, the composition of this claim is identical to the composition in the broad claim that Examiner Kulkosky rejected and did not allow in the '241 Application.

On December 5, 2002, Par filed a Power of Attorney with the PTO appointing Frommer Lawrence & Haug, LLP ("FLH") as attorneys of record in the '823 Application. (*Id*., pp. 38-39). Examiner George's first communication in the '823 Application was a Notice of Allowability issued on December 13, 2002. In the accompanying Statement of Reasons for Allowance, Examiner George stated:

> The claims are allowable over the prior art because the prior art does not teach, disclose nor make obvious a method of preparing an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol or sorbitol, and (b) a surfactant, provided that the combination does not consist of polyethylene glycol and polysorbate; and combining the solution with megestrol acetate.

The '823 Application issued as the '320 Patent on July 15, 2003, the same date on which the '318 Patent issued, and Par sued Roxane for infringement of both patents that same day. At no time during prosecution of the '823 Application did Par advise Examiner George of Examiner

Kulkosky's rejection of substantially similar claims in the '241 Application.

II. Grounds for Roxane's Motion

A. Failure to Disclose Examiner Kulkosky's Rejections: The principal ground for Roxane's charge that Par engaged in inequitable conduct is the fact that at no time during the prosecution of the patent applications at issue did Par advise Examiner George of Examiner Kulkosky's rejections in the '241 Application for obviousness and over breadth of claims of substantially the same scope as claims 19 and 41 of the '318 patent as issued. Further, Par represented to examiner George that the broad claim it was presenting in the '261 Application (which issued as the '318 Patent) covered "subject matter disclosed but not previously specifically claimed in this application or in the parent application/patents." In fact, new independent claims 41 and 63 (claims 19 and 41 as issued) claim the same subject matter, phrased in a slightly different way as the claims originally presented and rejected in the '241 Application.

B. Failure to Disclose BMS v. Par Litigation: BMS was the first company to develop an oral megestrol acetate liquid suspension product, and upon FDA approval began marketing it in the United States in 1993, under the brand name Megace®. On August 16, 1994, BMS obtained the '732 Atzinger Patent, which covers BMS's Megace® product.

Par's commercial product is a generic version of Megace® and like BMS's Megace®, Par's product is formulated as a flocculated suspension. In about 1996, when Par first decided to develop a generic version of BMS's Megace® product, Par set out to copy BMS's exact formulation. During the summer of 1997, Par learned of BMS's '732 Atzinger Patent, which covered the Megace® product. Par then set out to develop a product using a surfactant other than

polysorbate and/or a wetting agent other than polyethylene glycol ("PEG"), as the claims of the '732 Atzinger Patent are limited to that combination.

Par ultimately formulated its commercial product using another surfactant, docusate sodium, and two other wetting agents, propylene glycol and glycerin, (RLX 5, p.6), and in July, 1999, Par filed with the FDA an Abbreviated New Drug Application ("ANDA") seeking approval to market that product. As required by law, Par gave notice of its ANDA filing to BMS. See Pharm. Res., Inc., v. Roxane Labs., Inc., No. 03-3357 (DRD), 2006 WL 3231427, at *4 (D.N.J. Nov. 8, 2006) ("Roxane I"). On October 6, 1999 (while Par's '241 Application was still pending, and before Par's '841 Application was filed), BMS sued Par for infringement of the '732 Atzinger Patent. FLH, which had represented Par in its interference proceeding in the PTO with Alpharma, also represented Par in the litigation against BMS, and FLH attorney Dan Brown was again on FLH's litigation team.

The district court granted Par's motion for summary judgment of non-infringement, finding that prosecution history estoppel barred BMS from arguing that Par infringed the '732 Atzinger Patent under the doctrine of equivalents, Bristol-Myers Squibb Co. v. Par Pharmaceutical, Inc., No. 99 Civ. 10322 (LMM), 2000 WL 34500561, at *1 (S.D.N.Y. Dec. 22, 2000), ("BMS v. Par") and the Federal Circuit affirmed. Bristol-Myers Squibb Co. v. Par Pharmaceuticals, Inc., No. 01-1246, 2001 Fed. Appx. 816 (Fed. Cir. 2001). By virtue of this ruling the court did not address on the merits BMS's argument that docusate sodium and glycerin in Par's formulation were equivalent, respectively, to the polysorbate and PEG claimed in the '732 Atzinger Patent.

BMS v. Par was pending while Par was prosecuting the applications for the patents in

suit. Roxane notes that inventor Femia was a principal contact at Par for that litigation and that FLH attorney Brown worked on BMS v. Par on Par's behalf and was also assigned to work in the prosecution of Par's '261 and '823 Applications. He supervised Amy Leahy, an FLH patent agent, in her work on those applications. Roxane contends that Par's failure to advise the PTO at any time of the existence of that litigation or any prior art the existence of which it became aware during that litigation constituted inequitable conduct.

Prior to the trial of Roxane's claim that this is an exceptional case by reasons of Par's inequitable conduct, Par moved to exclude Roxane's newly advanced contention that the inequitable conduct included Par's failure to apprise the Examiner of the existence of the BMS v. Par litigation. The court reserved judgment on the motion. At the trial the court, over Par's continuing objections, admitted evidence concerning the litigation subject to its being struck if the court granted Par's motion to exclude. Having had the opportunity to review both Roxane's proffered evidence concerning this issue and the circumstances of Roxane's late advancement of the claim, the court will grant Par's motion to exclude and will not consider the evidence concerning Par's failure to advise the Examiner of the BMS v. Par litigation when deciding if this is an exceptional case.

Fed. R. Civ. P. 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other condition of a person's mind may be alleged generally." "[I]nequitable conduct, while a broader concept than fraud, must be with particularity." Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F. 3d 1347, 1356 (Fed. Cir. 2007).

Par filed its complaint in 2003. In its Third Amended Answer, Affirmative Defenses and

Counterclaims Roxane pled the following relevant affirmative defenses:

> Fifth Affirmative Defense: Unenforceability of the '318 Patent Based on Failure to Inform Patent Examiner of the Rejection of Substantially Identical Claims by a Prior Patent Examiner;
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> Sixth Affirmative Defense: Unenforceability of the '318 Patent Based on the Failure to Inform the Patent Examiner of Material Experimental Results;
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> Seventh Affirmative Defense: Unenforceability of the '318 Patent Based on the Failure to Inform the Patent Examiner of Prior Art References More Material than the Prior Art Known to the Patent Examiner;
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> Eighth Affirmative Defense: Unenforceability of the '318 Patent Based on the Failure to Inform the Patent Examiner of A Material Prior Art Commercial Formulation;
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> Ninth Affirmative Defense: Unenforceability of the '320 Patent Based on Failure to Advise the Patent Examiner of the Rejection of Substantially Identical Claims by a Prior Patent Examiner;
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> Tenth Affirmative Defense: Unenforceability of the '320 Patent Based on the Failure to inform the Patent Examiner of Material Experimental Results;
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> Eleventh Affirmative Defense: Unenforceability of the '320 Patent Based on the Failure to Inform the Patent Examiner of Prior Art References More Material than the Prior Art Known to the Patent Examiner; and
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> Twelfth Affirmative Defense: Unenforceability of the '320 Patent Based on the Failure to Inform the Patent Examiner of A Material Prior Art Commercial Formulation.

In April, 2006, Roxane moved for summary judgment that its product did not infringe the asserted claims, that the asserted claims are invalid for lack of enablement under 35 U.S.C. § 112, first paragraph, and that certain of those claims are invalid as obvious under 35 U.S.C. § 103 or are indefinite under 35 U.S.C. § 112, second paragraph.

On December 19, 2006, the Court entered final judgment (i) granting Roxane's motion for summary judgment of invalidity; (ii) dismissing any remaining counterclaims in the case

without prejudice, with the right of Roxane to have them restored to the calendar should the case be reinstated for any reason; (iii) staying Roxane's application for attorney fees pending a further order from this Court subsequent to a final decision upon Par's appeal of the December 19 order; and (iv) stating that Par has stipulated that in the event that Par is unsuccessful on its appeal, Roxane's application for attorney fees will be timely if filed on a date to be set by the Court after the stay herein is lifted. The Federal Circuit subsequently affirmed the Court's invalidity decision.

At a conference on December 20, 2007, the Court scheduled the trial on the issue of attorney fees, to start January 14, 2008. The Court directed (i) Roxane to provide Par with a list of witnesses and a summary of its inequitable conduct claims by December 26, 2006; and (ii) Par to provide Roxane with a list of witnesses by January 2, 2008. Pursuant to the Court's direction, Roxane provided Par a "summary" of [its] Inequitable Conduct Claim" by way of a December 26, 2007, letter which identified the affirmative defenses listed in Roxane's Third Amended Answer, Affirmative Defenses and Counterclaims. It did not state an allegation of inequitable conduct based on a failure to disclose the BMS litigation. Later that day Roxane sent Par an e-mail that sought to add an additional inequitable conduct allegation based on the BMS litigation. It stated:

> Further to the letter I sent you earlier today, I want to be clear that our attorneys fee claim for both patents, which relies on Par's inequitable conduct in failing to disclose Femia's testimony in the BMS v. Par litigation regarding failed experiments and Par's inequitable conduct in failing to disclose prior art it learned about during that litigation, is more generally premised on Par's complete failure to apprise the Examiner of the existence of that litigation.

In a January 2, 2008, letter Par objected to conducting the trial on January 14 and in

particular objected to Roxane's introducing its additional basis for its inequitable conduct claim. On January 13, 2008, Par filed its motion, returnable on January 14, for an order to exclude Roxane's new inequitable conduct claim. As stated above, the court reserved decision on the motion and proceeded with the trial, noting Par's continuing objection to evidence relating to the BMS litigation. The trial proceeded on January 14, 15, 16, 17 and 24, 2008.

Roxane advanced its inequitable conduct claim based on the BMS litigation much too late in the proceedings to give Par adequate notice and an opportunity to defend. It has not been the subject of either fact or expert discovery, and, in fact, was first raised after the close of discovery and final judgment. Par would be prejudiced by introducing this new contention at this time, as Par has not had the opportunity to conduct discovery on this issue. Consequently, Par's motion to exclude Roxane's inequitable conduct claim based on failure to advise the Examiner of the BMS litigation will be granted, and the evidence and arguments addressing that issue will not be considered in connection with Roxane's claim that this is an exceptional case based on Par's inequitable conduct. Evidence relating to the BMS litigation may, however, be relevant to other bases of Roxane's claim of inequitable conduct. There is an overlap in Roxane's failure to disclose the BMS litigation argument and Roxane's failure to disclose prior art argument. Much of the alleged prior art upon which Roxane relies was disclosed in the BMS litigation and can still be relied upon.

C. Par's Failed Experiments: Roxane cites the failure of Par to advise the Examiner that a number of its attempts to formulate stable flocculated suspensions of megestrol acetate failed. During the period from October, 1996 to September, 1999, Par prepared formulations with different surfactants. These surfactants included polysorbate, tergitol, sodium lauryl sulphate

("SLS"), cetyl trimethyl ammonium biomide ("CTAB"), BRIJ®[4], MYRJ®[5], and docusate sodium. At his deposition in BMS v. Par, inventor Femia testified that formulations made with four of the surfactants Par tested, SLS, CTAB, BRIJ®, and MYRJ®, did not meet the standard for stability set forth in Par's patent applications. Although the broad claims in Par's patent applications were to stable suspensions made with any surfactant at any concentration, Par did not advise the Examiner of the failures with respect to four of the seven surfactants it tested.

Par also failed to advise the Examiner that, as disclosed in a 1998 Progress Report drafted by inventor James Chao, that "two samples with 0.020 and 0.0225% wt/vol. [docusate sodium], respectively, deflocculated . . ." at one and a half months (instead of remaining stable for three months).

D. Failure to Disclose Prior Art: The prior art references referred to in the '241 Application were the '732 Atzinger Patent and references cited therein. Of these references only the Atzinger '732 Patent relates to the formulation of flocculated suspensions. The '241 Application also referred to a sentence from a treatise, Robert A. Nash, "Pharmaceutical Solutions", in Pharmaceutical Dosage Forms (Marcel Dekker, 1988) and also the 1989 Physicians Desk Reference showing the amount of polysorbate found in several pharmaceutical preparations for steroids other than megestrol acetate. During the prosecution of the applications at issue Par disclosed to the PTO a complaint filed by Alpharma seeking a declaration that Par's '065 Patent was invalid and a PTO notice advising Par of an interference proceeding regarding

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[4] BRIJ® is an ethoxylated alcohol, and ethoxylated alcohols are identified in Par's patents as suitable non-ionic surfactants.

[5] MYRJ® is polyethylene glycol monostearate, which is a type of polyoxyethylene glycol fatty acid ester, and such esters are identified as suitable non-ionic surfactants in Par's patents.

Par's '065 Patent. Roxane cites prior art that it asserts Par should have brought before the PTO.

The first category of such prior art are references consulted by the inventors during Par's development efforts. Among the references Femia reviewed were (1) Swarbrick, James, Coarse Dispersions, in Remington: The Science and Practice of Pharmacy, 278 - 279 (19th Ed., 1995) ("Remington") and (2) Storz, Gunther K., and Kennon, Lloyd, Pharmaceutical Suspensions, in The Theory and Practice of Industrial Pharmacy, 479-501 (3rd Ed., 1986) ("Lachman"). Remington and Lachman disclose surfactants other than polysorbate and wetting agents other than polyethylene glycol that can be used to formulate oral flocculated suspensions, information that was not before the PTO when it examined Par's applications for the suit patents. Femia testified that he would have advised Par's patent lawyers of these references; the Ostrolenk attorneys who drafted Par's applications for the suit patents testified that no one disclosed Remington or Lachman to them.

D. P. Patel, an experienced, long-time employee in Par's formulation group, assisted inventor Ragunathan. To learn more about formulating flocculated suspensions, Patel reviewed Remington and Lachman as well as articles Ragunathan provided him, including "Flocculations of Suspensions Containing Non-ionic Surfactants by Sorbitol", 76 J. Pharm. See 157 (1987) ("Zatz 2"). Zatz 2 taught, among other things, the formulation of flocculated suspensions with a surfactant, polysorbate, and wetting agent, sorbitol. Thus, like Remington and Lachman, Zatz 2 disclosed that a flocculated suspension could be formulated with a combination of a surfactant and a wetting agent different from the combination disclosed in the '732 Atzinger Patent. Zatz 2 was not submitted to the PTO.

The next category of prior art that Roxane asserts Par failed to submit to the PTO was

prior art that came to the attention of its attorneys or inventors during the course of the litigation of BMS V. Par. Par's expert, Dr. Stanley L. Hem, cited seven prior art references in his initial report; BMS's expert, Dr. Joel Zatz, cited eleven prior art references in his expert report, and in Hem's rebuttal expert report, Hem cited yet additional prior art references, including articles authored by Zatz. According to the Zatz report, it was well known in the art of pharmaceutical formulation to employ polyethylene glycol, propylene glycol, glycerin, and sorbitol as wetting agents in oral suspensions, and that the surfactants docusate sodium and polysorbate were known to function interchangeably in formulating stable flocculated suspensions. According to Roxane, information from the Zatz report was directly pertinent to Par's assertion to the PTO that it was "surprising' that megestrol acetate could be formulated as a stable flocculated suspension with surfactants other than polysorbate (the only surfactant specifically mentioned in the '732 Atzinger Patent), provided that one or more of the wetting agents polyethylene glycol, propylene glycol, glycerin and sorbitol were also present. This information from the Zatz report was not disclosed to the PTO.

In Hem's rebuttal expert report, Hem identified the following references, among others: (1) Joel Zatz, and Ru-Yun Lue, Effect of Polyols on Physical Stability of Suspensions Containing Nonionic Surfactants, 33 J. Soc. Cosmet. Chem. 149 (1982) ("Zatz 1"), which discloses, inter alia, the formulation of flocculated suspensions with a surfactant, polysorbate, and three different wetting agents, propylene glycol, PEG and sorbitol; (2) Joel Zatz and Ru-Yun Lue, Flocculation of Suspensions Containing Nonionic Surfactants by Sorbitol, 76 J. Pharm. Sci. 157 (1987) ("Zatz 2"), which discloses, inter alia, the formulation of flocculated suspensions with a surfactant, polysorbate and a wetting agent, sorbitol; and (3) Joel Zatz, Effect of Formulation

Additives on Flocculation of Dispersions Stabilized by a Non-Ionic Surfactant, 4 International Journal of Pharmaceutics, 83-86 (1979) ("Zatz 3"), which discloses, inter alia, the formulation of flocculated suspensions with a surfactant, polysorbate, and a wetting agent, propylene glycol.

Hem also criticized Dr. Zatz's conclusions based, inter alia, on M.R. Billany, Ch. 15, Suspensions, in Pharmaceutics: The Science of Dosage Form Design, 269-281 (Michael E. Aulton ed., 1988) ("Billany"), which Zatz had cited in his report and which taught, inter alia, that:

> [m]aterials such as alcohol, glycerol [aka glycerin] and glycols [e.g., propylene glycol and polyethylene glycol] which are water miscible will reduce the liquid/air interfacial tension. The solvent will penetrate the loose agglomerates of powder displacing the air from the pores of the individual particles thus enabling wetting to occur by the dispersion medium.

Like the information in Zatz's expert report, the prior art cited by Hem, i.e., the three Zatz articles and Billany, taught that prior to Par's invention it was well known to use a surfactant with wetting agents other than polyethylene glycol, including propylene glycol, glycerol and/or sorbitol, to form flocculated suspensions of insoluble drug substances. This prior art was not provided to the PTO.

E. Failure to Disclose Children's Motrin®: Roxane characterizes Children's Motrin® as prior art that should have been, but was not, disclosed to the PTO. Children's Motrin® is a liquid suspension of an insoluble drug, ibuprofen, that includes the combination of a surfactant, polysorbate, and a wetting agent, glycerin. It also includes the same buffer (citric acid), preservative (sodium benzoate), sweetener (sucrose), and thickener (xanthan gum) used in the three Examples in Par's applications for the suit patents.

On October 20, 1997, i.e., before Par filed its first application at issue, inventor

Ragunathan sent an e-mail to co-inventors Femia and James Chao, observing that the formulation of the Motrin® product he had purchased was "very similar" to the formulation Par was developing for its megestrol acetate suspension product, and that the active ingredient, ibuprofen, was not soluble in the suspension.

III. Discussion

A. Legal Principles: Under 35 U.S.C. § 285 a court may award reasonable attorney fees to the prevailing party in exceptional cases. Fee shifting should occur only in cases that are truly exceptional. Mathis v. Spears, 857 F.2d 749, 758 (Fed. Cir. 1988). "[T]he district court must (1) determine whether there is clear and convincing evidence that a case is exceptional, a factual determination reviewed for clear error, and (2) if so, then determine in its discretion whether an award of attorney fees is justified, a determination that [the Federal Circuit] review[s] for an abuse of discretion." Diego, Inc. v. Audible, Inc., 505 F.3d 1362, 1366-67 (Fed. Cir. 2007).

In the present case Roxane relies upon its allegation that Par engaged in inequitable conduct before the PTO to establish that the case is exceptional. To prove inequitable conduct, a moving party must establish by clear and convincing evidence that some individual with a duty of candor failed to disclose material information or submitted materially false information to the PTO during prosecution with intent to mislead or deceive the examiner. Digital Control Inc. v. Charles Mach. Works, 437 F. 3d 1309, 1313 (Fed. Cir. 2006); Purdue L.P. v. Boehringer Ingelheim GMBH, 237 F. 3d 1359, 1366 (Fed. Cir. 2001). Both "[m]ateriality and intent to deceive are distinct factual injuries, and each must be shown by clear and convincing evidence." Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F. 3d 1371, 1384 (Fed. Cir. 2005).

A prior art reference or item of information is material when "a reasonable examiner

would have considered such prior art or information important in deciding whether to allow the parent application." Digital Control, 437 F. 3d at 1314. Information or a reference that is cumulative of what is already part of the application record is not material to patentability. Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007). A finding of an intent to deceive requires that "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive. McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F. 3d 897, 913 (Fed. Cir. 2007).

Determining the knowledge and intent of the attorneys who worked on the applications and other proceedings in issue is particularly difficult because of the number of related proceedings, i.e., (i) the '241 Application leading to the '065 Patent, (ii) the '841 Application leading to the '356 Patent, (iii) the '261 Application leading to the '318 Patent, (iv) the interference proceeding, (v) the '823 Application leading to the '320 Patent, and (vi) the BMS v. Par patent case. Further complicating the situation is the fact that different lawyers and law firms worked on different matters, and on occasion different law firms were substituted to work on the same matter.

B. Failure to Disclose Examiner Kulkosky's Rejections: Examiner Kulkosky's rejection in the '241 Application of Claims 1-22 on the ground that they comprised formulas whose stability was not a definite range and Par's narrowing of those claims to both specify ranges of ingredient amounts and to define the stability of the claimed suspensions was information that a subsequent examiner would have considered important in deciding whether to allow the subsequent Par applications. Thus it was material.

Roxane, however, has not established by clear and convincing evidence that the failure of Dr. Femia, the various attorneys and others who dealt with the Examiners on Par's behalf intended to deceive the Examiner when they failed to mention this aspect of the processing of the '241 Application. The prior rejections were part of the record. There was testimony on Roxane's behalf that Examiner George or Supervising Examiner Dees would not likely have gone back to examine the record in the '241 Application. However, there was countervailing evidence that the Examiners, regardless of information provided by Par's attorneys, would have considered that record. Par made it clear to the PTO that the earlier '241 Application was part of the record in the '261 and '823 Applications. It is likely that the two Examiners responsible for the examination of the '261 and '823 Applications would have considered the earlier rejections because they rejected the then-pending claims based on double patenting over earlier '065 and '356 Patents. Examiner Greene and Supervisory Examiner Dees, to comply with their duty to give full faith and credit to actions by previous Examiner Kulkosky, would have had to have reviewed the earlier actions. MPEP § 704.01 (Aug. 2001). Further, a continuing application flows from a parent application and has the benefit of the file history from the parent case. MPEP § 2001.11 (Aug. 2001). The '261 and '823 Applications were of the continuing-application type, and "[i]n all continuing applications, the parent application should be reviewed by the examiner for pertinent prior art." MPEP § 904 (Aug. 2001). This distinguishes this case from rejections of similar claims by a different examiner in a separate family of applications, e.g., Dayco Prods., Inc. v. Total Containment, Inc., 329 F. 3d 1358 (Fed. Cir. 2003). Most likely the Par inventors and attorneys assumed that the Examiners would become familiar with the file history and that it would be unnecessary to bring parts of it to their attention.

A series of Par attorneys dealt with the PTO over a period of time as assignments changed and as one law firm replaced another. For example: Mr. Gray of the Ostrolenk firm signed the November 15, 2001, Second Preliminary Amendment, although it was written by attorney Edward Meilman of that firm. Mr. Meilman had stopped working on the '261 Application, having given notice that he was leaving the Ostrolenk firm to join another firm. On April 30, 2002 Ostrokenk filed the '823 Application as a division of the '261 Application. Inventor Robert Femia was Par's principal contact for Par's patent applications and as such reviewed substantive submissions to the PTO. Par was represented in the interference proceedings by the law firm of FLH, including FLH attorney Daniel Brown. On November 27, 2002 Par appointed FLH as attorneys of record in the '261 Application, filing a Comments on Statement for Reasons of Allowance signed by FLH patent agent Amy Leahy. Both Brown and Leahy worked on the prosecution of the '261 and '823 Applications.

The Par personnel processing the Applications after Examiner Greene became the Examiner with whom they dealt were entitled to assume that Examiner Greene would become familiar with the antecedent record and that there would be no need to bring particular parts of the record to his attention. Meilman of the Ostrolenk firm testified that the Examiner would have to read what the Examiner did in the previous case. There is no evidence that Mr. Meilman acted to deceive the Examiner.

There is no evidence that Charles Ochkar, Ph.D., even considered whether Examiner Kulkosky's rejections in the '241 Application were material to the patentability of the claims in the '261 and '823 Applications, much less that he had an intent to deceive by withholding information about the '241 Application file history. William O'Gray, III, was not shown to have

been aware of the rejections in the '241 Application and did not work in the prosecution of that Application. Thus he could not have intended to withheld material information and necessarily lacked an intent to deceive.

Daniel G. Brown's involvement with Par's patents began when he represented Par in an interference proceeding against a third party, Alpharma, in June 2002. Following that proceeding, FLH was made attorney of record in the '261 and '823 Applications in November and December 2002, respectively. Mr. Brown was not assigned to work on the original prosecution of the '261 Application, and during his work on the interference proceeding he had no reason to consider the rejections in the file history of the '241 Application.

FLH became attorneys of record after the interference and simply built on the work that had been done by previous attorneys. The testimony of Dr. Amy Leahy, a patent agent at FLH, disclosed how unfamiliar she was with all the proceedings that had gone before. She filed two innocuous documents prepared six months earlier by Mr. Gray. Another document FLH filed communicated the same substance as Mr. Gray's earlier Comments. There were other limited communications between FLH, (through Mr. Brown and Dr. Leahy) and the Examiner concerning the '823 Application but there is no evidence that even if Mr. Brown and Dr. Leahy were aware of Examiner Kulkosky's rejections in the '241 Application that any of the communications were made with an intent to deceive.

Roxane places emphasis upon Par's remarks contained in its November 15, 2001, Preliminary Amendment adding new composition claims to the effect that:

> A series of new claims covering subject matter disclosed but not previously specifically claimed in this application or in the parent applications/patents is being presented for consideration by the Examiner.

Roxane characterizes this as a misrepresentation, citing the similarity of claims 41 and 63 added to the '261 Application by Par's second Preliminary Amendment to claim 1 from the '241 Application as filed, which Examiner Kulkosky rejected and never allowed. There were differences between the new claims and claim 1 from the '241 Application; and thus the statement contained in the Preliminary Amendment was not literally a misrepresentation. Roxane can, and does, argue that the statement is indicative of an intent to deceive because the new claims are similar to Claim 1 of the '241 Application in that they are as broad as the original Claim 1. In view of the other considerations discussed above, this statement in the Preliminary Amendment is insufficient to establish an intent to deceive.

In summary, Par's representatives, dealing with Examiner Greene and Supervising Examiner Dees, including Dr. Femia, most likely assumed that Examiner Greene would familiarize himself with the '241 Application file history and would have no reason to withheld from him for ulterior purposes the fact of Examiner Kulkosky's rejections. Morever, Roxane's evidence does not establish an intent to deceive on the part of any of Par's many representatives dealing with the PTO.

C. Par's "Failed Experiments": Citing Dr. Femia's testimony in the BMS v. Par litigation, Roxane contends that four out of seven surfactants with which Par experimented did not meet the standard for stability set forth in Par's patent applications, i.e., formulations made with these surfactants did not yield flocculated suspensions of megestrol acetate that remained stable for three months.

According to Dr. Femia's testimony, in early development work, such as preliminary experiments, the inventors only performed visual assessment and sedimentation height tests in

order to select promising candidate formulations for further development. All the surfactants tested resulted in stable floccules and thus gave promise of producing stable megestrol acetate suspension.

Dr. Ragunathan testified that the suspensions derived from the surfactant MYRJ® remained redispersible for a period of five years. Dr. Femia further testified that the BMS litigation concerned the stability of Par's product relative to BMS's brand product. Thus the experiments which Roxane characterizes as "failed," were failed only in the sense that they were less stable when compared to BMS's brand product for the purposes of gaining FDA approval: "In all cases studied, we had flochs stable, stable flochs present. Whether or not that was the same extent of the flocculation of that the brand product had would have been the determining factor for the more or less arbitrary statement that it was not stable or it was stable... And in my opinion, most of the formulations, if not all the ones that we tried with a variety of surfactants listed would have been stable had we continued to look at them, and perhaps some of them might have required a little modification." (Hr'g Tr. 82:4-9, 82:21-83:2, Jan. 15, 2008).

An applicant need not disclose to the PTO each success and failure encountered in the course of the development of its inventive product or process. The results of the experiments about formulations made with SLS, CTAB, BRIJ® and MYRJ® were not material information that Par was required to disclose to the PTO. If it were, the evidence does not support a finding that any of Par's representatives who were award of these experiments failed to disclose them to the PTO with an intent to deceive.

D. Non-Disclosure of Prior Art References: It is Par's contention, supported by the testimony of Dr. Femia and Par's technical expert, Dr. Klibanov, that the only reference

identified by Roxane that was relevant to the patentability of the '318 and the '320 patents was the Atzinger Patent. That patent teaches that the formation of stable flocculated suspension of megestrol acetate requires the specific combination of a polysorbate with polyethylene glycol. According to Atzinger, successful applications for other steroids cannot be applied to megestrol acetate. As Dr. Klibanov testified based on the teachings of Atzinger: "what works for the other steroids does not work for the steroid megestrol acetate" - "what would otherwise be predictable based on the prior art teachings, does not apply when the drug is megestrol acetate." (Hr'g Tr. 35:12-13, 41:6-16, Jan. 24, 2008).

Roxane at one time, at least, was in agreement with this view of Atzinger's teaching. Its inventors concluded:

> Atzinger, et al. also disclose that megestrol acetate flocculated suspensions are unique because what would otherwise be predictable based on the prior art teachings does not apply when the drug is megestrol acetate.

Undoubtedly for this reason, none of the references that Roxane now alleges were withheld from the PTO as part of an intent to deceive were disclosed by Roxane in its own patent application.

Following this reasoning, none of the references upon which Roxane relies were prior art. Each concerned steroidal compounds other than megestrol acetate, which does not behave structurally like other similar steroidal compounds. The drugs in the Zatz and Billany articles are not steroids and are simpler and structurally different from megestrol acetate. Similarly the Nash, Remington and Lachman references did not disclose megestrol acetate.

For this reason these articles were not material prior art. Clear and convincing evidence does not establish that the inventors or attorneys were aware of the Zatz or Billany articles at the

relevant time, nor does clear and convincing evidence establish that the inventors or attorneys failed to disclose these references with the intent to deceive the PTO. Similarly, it is to be assumed that Roxane's inventors and attorneys did not intend to deceive the PTO when Roxane failed to disclose these references in a parallel patent application.

Even more remote from the '318 and '320 patents is the Motrin® formulation which Roxane alleges "was more pertinent than any prior art made known to the Patent Examiner" during the prosecution of the '318 and '320 patents. Dr. Klibanov testified that the Motrin® formulation is not material or relevant to the patentability of those patents. Roxane's expert, Dr. Brittain, agreed that the Motrin® formulation neither contains megestrol acetate nor is a flocculated suspension.

Motrin®'s active ingredient is Ibuprofen, which is not a steroidal compound. Ibuprofen has limited water solubility, while megestrol acetate "is as close to being totally unsoluble in water as you can get." (Hr'g Tr. 91:10-12, Jan. 15, 2008). Therefore, megestrol acetate and ibuprofen behave very differently in forming a suspension with floccules (Hr'g Tr. 91:12-16, Jan. 15, 2008). Motrin® was not a material reference which Par's inventors or attorneys were required to disclose to the PTO.

Moreover, clear and convincing evidence does not establish that Par's inventors or attorneys considered Motrin® relevant to preparing megestrol acetate suspensions or, by not disclosing it, had an intent to deceive the PTO.

Conclusion

For the foregoing reasons the court finds that Roxane has failed to establish by clear and convincing evidence that Par withheld from, or misrepresented to, the PTO material information

with the intent to mislead the PTO. Consequently, Roxane has not established that this is an exceptional case entitling it to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285. Par's motion in limine to exclude Roxane's claim of inequitable conduct based on Par's failure to disclose the BMS litigation to the PTO will be granted. Roxane's motion for attorney fees will be denied. The court will file an appropriate order implementing this opinion.

Dated: April 9, 2008

/s/ Dickinson R. Debevoise
DICKINSON R. DEBEVOISE
U.S.S.D.J.